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K001685

510 (k) SUMMARY

Submitter's name: **Address:**	Ann Marie Pahlman MPGR A-2E 1620 Waukegan Rd. McGaw Park, IL 60085
Phone: **Fax:**	847-473-6078 847-473-6952
Contact: **Date Prepared:**	Ann Marie Pahlman or Robert L. Wilkinson May 31, 2000
Trade name: **Common name:** **Classification name:**	PSN™ Hemodialyzer, for single or multiple use Hemodialyzer Hemodialysis Systems and Accessories per 21 CFR 87.5820 and High Permeability Hemodialysis System per 21 CFR 876.5860
Equivalent predicate:	PSN™ Hemodialyzers, for single use
Device Description:	Model 130, Model 150, Model 170 and Model 210 Hemodialyzers
Intended Use:	Intended specifically for use in patients with acute or chronic renal failure when conservative therapy is judged to be inadequate. It may also be indicated in the treatment of patients intoxicated with poisons or drugs.
Summary of the technological predicate device	The general function and materials of the subject PSN™ Hemodialyzers are the same as the Baxter PSN™ Hemodialyzers cleared under K980656 and K980658
Clinical data:	N/A
Conclusions drawn:	Components of the subject PSN™ Hemodialyzers have met the biological requirements of ISO 10993-1: Biological Evaluation of Medical Devices – Part: Guidance on selection of tests. The validation of the sterilization cycle for the PSN™ Hemodialyzer is based upon the Association for the Advancement of Medical Instrumentation (AAMI) Guidelines (ST-27-Industrial Ethylene Oxide (EO)

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May 31, 2000
PSN™ Hemodialyzer

Pyrogen testing of the subject dialyzers meets the requirements of Chapter 161, Transfusion and Infusion Assemblies and Similar Medical Devices of Supplement 2 of the USP.

Particles are counted per USP XXIII <788>.

Functional testing for blood side integrity and conformance to manufacturing specifications are performed as in-process and/or final inspections prior to product release ensuring a quality product.

In vivo and *In vitro* performance data, and directions for Reuse have been included in the labeling.

Additional information requested by FDA: none to date.

Official Correspondent:

Robert L. Wilkinson — 5/31/00
Robert L. Wilkinson
Director, Regulatory Affairs
Date

Prepared by:

Ann Marie Pahlman — 5/31/00
Ann Marie Pahlman
Manager, Regulatory Affairs
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Robert L. Wilkinson
Director, Regulatory Affairs
Baxter Healthcare Corporation
Renal Division, MPR-A2E
1620 Waukegan Road
MCGAW PARK IL 60085-6730

Re: K001685
Multiple Use Labeling for the Baxter PSN™
Hemodialyzers, Models 130, 150, 170 and 210
Dated: September 21, 2000
Received: September 22, 2000
Regulatory Class: II
21 CFR §876.5820/Procode: 78 MSE
21 CFR §876.5860/Procode: 78 MSF

Dear Mr. Wilkinson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Indications for Use Statement

510(k) Number (if known): K001685

Device Name: PSN™ Hemodialyzer, for Single or Multiple Use
Models 130, 150, 170, 210

Indications For Use: Hemodialysis with these dialyzers is indicated for patients with acute or chronic renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs. The device should be used only on the direction of a physician. This dialyzer is indicated for single use or reuse. If the dialyzer is reused on the same patient, the reuse procedure and disinfectant specified in this Direction Insert must be followed. No other reuse procedure or disinfectant has been evaluated for clinical acceptability.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001685